



Medical Necessity Criteria for Flector (diclofenac topical solution) and Pennsaid (diclofenac patch)

Drug Class – Topical Pain

Background – After evaluating the relative clinical and cost effectiveness of these agents, the DoD P&T Committee recommended that the following medications be designated as non-formulary under the Uniform Formulary. This recommendation has been approved by the Director, TMA.

- Diclofenac solution (Pennsaid)
- Diclofenac patch (Flector)

Medical Necessity Criteria for Flector and Pennsaid

Diclofenac patch (Flector)

The non-formulary cost share for Flector may be reduced to the formulary cost share if the patient meets any of the following criteria:

1. Patient has experienced significant adverse effects from ALL of the formulary medications that are not expected to occur with the non-formulary topical pain medication (e.g., patient experienced intolerable dry skin with use of diclofenac gel and has gastrointestinal or cardiovascular risk factors that preclude use of oral NSAIDs).
2. No alternative formulary agent – patient requires use of patch for treatment of pain associated with acute strain/sprain and cannot use oral NSAIDs or diclofenac gel products.

Diclofenac solution (Pennsaid)

The non-formulary cost share for Pennsaid may be reduced to the formulary cost share if the patient meets any of the following criteria:

1. Patient has experienced significant adverse effects from ALL of the formulary medications that are not expected to occur with the non-formulary topical pain medication (e.g., patient had intolerable dry skin with use of diclofenac gel and has gastrointestinal or cardiovascular risk factors that preclude use of oral NSAIDs).
2. Formulary agents result or are likely to result in therapeutic failure (e.g., patient had intolerable dry skin with use of diclofenac gel and has gastrointestinal or cardiovascular risk factors that preclude use of oral NSAIDs).
3. No alternative formulary agent – patient requires topical agent with dimethyl sulfoxide (DMSO) to aid in skin absorption.

Criteria approved through the DOD P&T Committee process

TRICARE Pharmacy Program Medical Necessity Form for
diclofenac patch (**Flector**) and diclofenac solution (**Pennsaid**)



6010

This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- **Diclofenac topical gel (Voltaren gel) and most oral nonsteroidal antiinflammatory drugs (NSAIDs) are the formulary agents in this drug class.** Diclofenac patch (Flector) and diclofenac topical solution (Pennsaid) are non-formulary, but available to most beneficiaries at the non-formulary cost share. (Other non-formulary NSAID agents include Cambia, Duexis, Naprelan CR, Ponstel, Sprix, and Zipsor.)
- You do NOT need to complete this form in order for non-active duty beneficiaries (spouses, dependents, and retirees) to obtain non-formulary medications at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication instead of a formulary medication is medically necessary. If a non-formulary medication is determined to be medically necessary, non-active duty beneficiaries may obtain it at the formulary cost share.
- Active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary. There is no cost share for active duty service members at any DoD pharmacy point of service.

MAIL ORDER and RETAIL	<ul style="list-style-type: none">• The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477• The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TPharmPA@express-scripts.com	MTF	<ul style="list-style-type: none">• Non-formulary medications are available at MTFs only if both of the following are met:<ul style="list-style-type: none">▪ The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.▪ The non-formulary medication is determined to be medically necessary.• Please contact your local MTF for more information. There are no cost shares at MTFs.
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Step 1 Please complete patient and physician information (please print):

Patient Name: _____	Physician Name: _____
Address: _____	Address: _____
Sponsor ID#: _____	Phone #: _____
Date of Birth: _____	Secure Fax #: _____

Step 2

Please explain why the patient cannot be treated with the formulary medications. Circle a reason code if it applies.
*** You MUST supply a specific written clinical explanation as to why each of the formulary medications would be unacceptable.

Formulary Medications	Reason	Clinical Explanation
Diclofenac topical gel (Voltaren gel)	1 2 3 4	
Oral NSAIDs	1 2 3 4	

Applicable clinical reasons for not using a formulary medication are:

1. Patient has experienced or is likely to experience significant adverse effects from all formulary medications that are not expected to occur with the non-formulary medication.
2. **(applies to Pennsaid only)** Use of the formulary medication(s) has resulted in or is likely to result in therapeutic failure.
3. **(applies to Pennsaid only)** Patient requires a topical agent with dimethyl sulfoxide (DMSO) to aid in skin absorption.
4. **(applies to Flector only)** Patient requires use of patch for treatment of pain associated with acute strain/sprain and cannot use diclofenac gel or oral NSAIDs products.

Step 3 I certify the above is correct and accurate to the best of my knowledge. Please sign and date:

_____	_____
Prescriber Signature	Date